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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,447	02/05/2004	David Edwards	000166.0109-US04	3817

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COVINGTON & BURLING
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1201 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20004-2401

EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/771,447	EDWARDS ET. AL	
	Examiner	Art Unit	
	Mital B. Patel	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-13 is/are allowed.
- 6) ☐ Claim(s) 14, 15, 18-22 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/23/05 has been entered.

Response to Amendment/Arguments

2. Applicant's arguments filed 5/23/05 have been fully considered but they are not persuasive.

3. In response to Applicant's arguments and amendment to recite the feature of a hemispheric region with a plurality of apertures, Applicant states that the Examiner noted as **part** of the statement for reasons for allowance. The Examiner would like to reiterate that , the particular feature was merely part of the reasons for allowance as there were other noted features which in combination with the plurality of apertures made the noted allowable claims allowable.

4. With respect to the amended feature of a hemispheric region with a plurality of apertures, the Examiner directs Applicant's attention to page 9, paragraph 54 of the specification, which discloses that "it should be understood that the present invention is not limited to a particular number of apertures **224**, and can be configured such that at

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least one aperture **224** is provided.” Such a disclosure is indicative of a lack of criticality for there being a plurality of apertures and thus, such a feature would be obvious to one of ordinary skill in the art to arrive at as a mere design choice.

5. In conclusion, the Examiner maintains the rejections set forth in the previous office action including the rejection having to do with the specific flow rate as there was sufficient motivation provide by the Examiner.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 14, 15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavazza (US 4,338,931) in view of Volgyesi (US 6,575,160).

10. **As to claim 14**, Cavazza teaches a method for dispensing powder by inhalation (**See Col. 4, lines 28-38**), comprising providing a powder inhalation device (**See Figs. 6-8**) that comprises, a casing **111** comprising at least one aperture **126A** configured to emit an emitted dose of the powder therethrough, and a cylindrical chamber **113A**, defined by a straight wall of circular-cross section (**See figs. 7-8**), disposed in said casing **111**, said chamber comprising a ring (**formed by 118 via 119**) circumferentially coupled to an inner surface of said chamber (**See Fig. 8**). Cavazza teaches essentially all of the limitations except for inhaling the emitted dose through said at least one aperture at a flow rate less than about 15 L/min. However, Volgyesi teaches a method for dispensing powder by inhaling at a flow rate of 8 L/min. in order to sufficiently fluidize the powder (**See Col. 6, lines 50-60 of Volgyesi**). Furthermore, Volgyesi teaches that the flow rate at which the powder is fluidized will depend on the type of dry powder formulation. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to look at the teaching of Volgyesi to determine a sufficient flow rate at which to inhale the emitted dose in order to sufficiently fluidize the powder and Volgyesi teaches this flow rate to be 8 L/min, a rate which is less than 15 L/min.

Furthermore, it would have been obvious to one of ordinary skill in the art that depending on the particular formulation of the powder, the flow rate at which the emitted dose is inhaled would vary as disclosed by Volgyesi. With respect to the amended feature of a hemispheric region with a plurality of apertures, the Examiner directs Applicant's attention to page 9, paragraph 54 of the specification, which discloses that "it should be understood that the present invention is not limited to a particular number of apertures **224**, and can be configured such that at least one aperture **224** is provided." Such a disclosure is indicative of a lack of criticality for there being a plurality of apertures and thus, such a feature would be obvious to one of ordinary skill in the art to arrive at as a mere design choice.

11. **As to claim 15**, Cavazza teaches a method further comprising prior to said inhaling: puncturing (via **120**) a receptacle **CP** containing the powder to disperse the powder in said chamber (**See Col. 4, lines 18-38**).

12. **As to claim 18**, Cavazza teaches a method wherein said ring (formed by **118** via **119**) is disposed approximately a midpoint (**See Figs. 7-8 which show that 118 is at the halfway mark of casing 111**) of said chamber **113A**.

13. **As to claim 19**, Cavazza teaches a method wherein said ring (formed by **118** via **119**) is disposed adjacent (**please note that the term adjacent is relative and the Examiner considers the location of the ring 118 to be adjacent/next to the proximal end of the chamber**) a proximal end (end near **114A**) of said chamber **113A**.

14. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavazza (US 4,338,931).

15. **As to claim 20**, Cavazza teaches a method for dispensing powder by inhalation (See Col. 4, lines 28-38), comprising providing a powder inhalation device (See Figs. 6-8) that comprises, a casing 111 comprising a first casing portion and a second casing portion, said first casing portion comprising at least one aperture 126A configured to emit an emitted dose of the powder therethrough, and a cylindrical chamber 113A, defined by a straight wall of circular-cross section (See figs. 7-8), disposed in said second casing portion, said chamber comprising a ring (formed by 118 via 119) circumferentially coupled to an inner surface of said chamber (See Fig. 8). With respect to the amended feature of a hemispheric region with a plurality of apertures, the Examiner directs Applicant's attention to page 9, paragraph 54 of the specification, which discloses that "it should be understood that the present invention is not limited to a particular number of apertures 224, and can be configured such that at least one aperture 224 is provided." Such a disclosure is indicative of a lack of criticality for there being a plurality of apertures and thus, such a feature would be obvious to one of ordinary skill in the art to arrive at as a mere design choice.

16. **As to claim 21**, Cavazza teaches a method further comprising prior to said inhaling, puncturing a receptacle CP containing the powder to disperse the powder in said chamber.

17. **As to claim 22**, Cavazza teaches essentially all of the limitations except for wherein the puncturing step is carried out using a substantially U-shaped staple. Cavazza instead teaches a linear shaped staple or needle for puncturing. One of ordinary skill in the art at the time of the invention would expect Applicant's invention to

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work equally as well with the puncturing means of Cavazza since the ability of the puncturing means to puncture the receptacle is not altered by the shape of the puncturing means.

Allowable Subject Matter

18. Claims 1-13 are allowed over the prior art of record.

19. Claims 16-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. The following is a statement of reasons for the indication of allowable subject matter: As to claim 1, the prior art of record does not teach nor render obvious the overall claimed combination of a method for dispensing powder by inhalation having a ring circumferentially coupled to an inner surface of a cylindrical chamber coupled to a first casing portion and an inhalation portion comprising a hemispheric region defining a plurality of apertures located in a second casing portion. It should be noted that the closest prior art of record is to Cavazza (US 4,388,931). However Cavazza in the embodiment of Figs. 6-8 teaches an inhalation portion in the first casing rather than the second casing. Furthermore, Cavazza does not teach a hemispheric region with a plurality of apertures. In the embodiment of Figs. 1-5, Cavazza does not teach a ring circumferentially coupled to an inner surface of a chamber coupled to the first casing portion. There is no motivation in the prior art of record to modify the device of Cavazza to arrive at the method recited in claim 1. As to claim 16, the prior art of record does not

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teach nor render obvious the overall claimed combination of the method for dispensing powder by inhalation wherein the puncturing step is carried out using a U-shaped staple having the particulars set forth in claim 16. It would not be an obvious design choice to use any puncturing device such as that taught by Cavazza since Applicant sets forth criticality in the specification as to the specifics of the U-shaped staple providing for improved puncturing and drug delivery. The puncturing device of Cavazza would not provide the same function since it is different structurally from that of Applicant's.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 6/26/05
Mital B. Patel

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